

Issued by the
UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SUBPOENA IN A CIVIL CASE

IN RE: '318 PATENT INFRINGEMENT
LITIGATION

Civil Action 05-356-KAJ (consolidated)
No.¹ District of Delaware

TO: Kenneth Davis
 160 Cold Spring Rd.
 Syosset, New York 11791

☐ YOU ARE COMMANDED to appear in the United States District court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case.

PLACE OF DEPOSITION Kirkland & Ellis LLP, Citigroup Center, 153 East 53 rd Street, New York, NY 10022-4611	DATE AND TIME January 18, 2006 at 9:00 AM
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☒ YOU ARE COMMANDED to produce and permit inspection and copying of the following documents or objects at the place, date, and time specified below (list documents or objects):
See attached Schedule A.

PLACE Kirkland & Ellis LLP, Citigroup Center, 153 East 53 rd Street, New York, NY 10022-4611 c/o Jay P. Lefkowitz	DATE AND TIME January 11, 2006 at 5:00 PM
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☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME
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Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER'S SIGNATURE AND TITLE (INDICATE IF ATTORNEY FOR PLAINTIFF OR DEFENDANT)  Attorney for Defendant	DATE December 28, 2005
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ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER
Edward C. Donovan, Kirkland & Ellis LLP, 655 15th Street, NW, Ste. 1200, Washington, DC 20005 (202) 879-5289

(See Rule 45, Federal Rules of Civil Procedure, Parts C & D on next page)

¹ If action is pending in district other than district of issuance, state district under case number.

AO88 (Rev. 1/94) Subpoena in a Civil Case

PROOF OF SERVICE

DATE

PLACE

SERVED ON (PRINT NAME)

MANNER OF SERVICE

SERVED BY (PRINT NAME)

TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on

DATE

SIGNATURE OF SERVER

ADDRESS OF SERVER

Rule 45, Federal Rules of Civil Procedure, Parts C & D:**(c) PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.**

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction which may include, but is not limited to, lost earnings and reasonable attorney's fee.

(2) (A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for deposition, hearing or trial.

(B) Subject to paragraph (d) (2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy materials or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3) (A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it

- (i) fails to allow reasonable time for compliance,
- (ii) requires a person who is not a party or an officer of a

party to travel to a place more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c) (3) (B) (iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or

(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or

(iv) subjects a person to undue burden.

(B) If a subpoena

(i) requires disclosure of a trade secret or other confidential research, development, or commercial information, or

(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or

(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena, or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA.

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

SCHEDULE A

DEFINITIONS

1. “Bonnie Davis” shall mean Bonnie Davis, the inventor of the ‘318 patent (as defined below), and any present or former employees, agents, representatives, or persons acting on behalf of Bonnie Davis.

2. “Janssen Pharmaceutica” shall mean Janssen Pharmaceutica N.V., a named plaintiff to the Current Litigation, and, a corporation organized and existing under the laws of Belgium, and any of its present or former divisions, and shall also include any present or former parent, subsidiary, affiliated or related corporation or any other related entity of Janssen Pharmaceutica N.V., including Janssen, L.P. “Janssen Pharmaceutica” shall further mean all past or present directors, officers, employees, agents, representatives, or persons acting on behalf of any of the foregoing entities.

3. “Janssen” shall mean Janssen, L.P., a named plaintiff to the Current Litigation, and a corporation organized and existing under the laws of the State of New Jersey, and any of its present or former divisions, and shall also include any present or former parent, subsidiary, affiliated or related corporation or any other related entity of Janssen, L.P. “Janssen” shall further mean all past or present directors, officers, employees, agents, representatives, or persons acting on behalf of any of the foregoing entities.

4. “Synaptech” shall mean Synaptech, Inc., a named plaintiff to the Current Litigation, and a corporation organized and existing under the laws of the State of New York, and any of its present or former divisions, and shall also include any present or former parent, subsidiary, affiliated or related corporation or any other related entity of Synaptech, Inc.

“Synaptech” shall further mean all past or present directors, officers, employees, agents, representatives, or persons acting on behalf of any of the foregoing entities.

5. “Intelligen” shall mean Intelligen, Corp., a corporation organized and existing under the laws of the State of New York, and any of its present or former divisions, and shall also include any present or former parent, subsidiary, affiliated or related corporation or any other related entity of Intelligen, Corp. “Intelligen” shall further mean all past or present directors, officers, employees, agents, representatives, or persons acting on behalf of any of the foregoing entities.

6. “ANDA” shall mean an abbreviated new drug application as provided under 21 U.S.C. § 355(j), and the corresponding implementing regulations at 21 C.F.R. § 314 *et seq.*

7. “NDA” shall mean New Drug Application No. 21-169 filed with the FDA and held by Janssen.

8. “The ‘318 patent” shall mean U.S. Patent No. 4,663,318, issued on May 5, 1987, and related Application No. 819,141.

9. “Application No. 819,141” shall mean the application filed by or on behalf of Bonnie Davis, on or about January 15, 1986, that eventually issued as the ‘318 patent.

10. “Current Litigation” shall mean the lawsuit entitled *In re ‘318 Patent Infringement Litigation*, Civil Action No. 05-356-KAJ (consolidated), pending in the United States District Court for the District of Delaware.

11. “Related Litigation” shall mean any lawsuit filed by Janssen, Janssen, L.P. and/or Synaptech wherein Janssen, Janssen, L.P. and/or Synaptech assert the ‘318 patent.

12. “Galantamine” shall mean the chemical compound (4a*S*,6*R*,8a*S*)-4a,5,9,10,11,12-hexahydro-3-methoxy-11-methyl-6*H*-benzofuro[3a,3,2-

ef][2]benzazepin-6-ol hydrobromide, which is the active pharmaceutical ingredient in pharmaceutical products approved by FDA for the treatment of mild to moderate dementia of the Alzheimer's type, also known as "Galanthamine."

13. "PTO" shall mean the U.S. Patent and Trademark Office.

14. "FDA" shall mean the U.S. Food and Drug Administration.

15. The terms "you" and "your" mean Kenneth Davis and any employees, agents, representatives, or persons acting on behalf of Kenneth Davis.

16. The term "communication" means the transmittal of information (in the form of facts, ideas, inquiries or otherwise).

17. The term "document" or "documents" is used herein in a comprehensive sense as set forth in Rule 34(a) of the Federal Rules of Civil Procedure, and shall be defined to include, without limitation, all tangible things, all written, printed, typed, photocopies, photographic, graphic or recorded matter of any kind, any recorded material however produced or reproduced, including agreements, books, calendars, charts, contracts, communications, computer databases, computer memory media, computer printouts, correspondence, desk pads, diaries, drafts, drawings, entries in books of account, electronic mail, facsimile transmissions, files, folders, graphs, guidelines, instructions, lists, manuals, memoranda, minutes, notes, operating procedures, pamphlets, reports, rules, studies, telegrams, teletypes, and all written or tangible things that can be derived from any computer database, microfilm, microfiche, or other storage medium. A draft or non-identical copy is a separate document within the meaning of this term.

18. The term "person" is defined as any natural person or any business, legal or governmental entity or association.

19. When referring to a person, "identify" means to give, to the extent known, the person's full name, present or last known address, and when referring to a natural person, additionally, the present or last known place of employment.

20. When referring to documents, "identify" means to give, to the extent known, the: (i) type of document; (ii) general subject matter; (iii) date of the document; and (iv) author(s), addressee(s), and recipient(s).

21. The term "concerning" means relating to, referring to, describing, evidencing, or constituting.

22. Something is "relating to" a subject if it makes a statement about, refers to, mentions, discusses, describes, reflects, deals with, consists of, constitutes, comprises, concerns, evidences, records, or in any way pertains to the subject, either in whole or in part, and either directly or indirectly.

23. The terms "all" and "each" shall be construed as all and each.

24. The connectives "and" and "or" shall be construed either disjunctively or conjunctively as necessary to bring within the scope of the discovery request all responses that might otherwise be construed to be outside its scope.

25. The use of the singular form of any word includes the plural and vice versa.

26. The term "including" means without limitation.

INSTRUCTIONS

1. No request shall be construed with reference to any other request for purposes of limitation.

2. Each requested document shall be produced in its entirety, including all attachments and enclosures. If a portion of a document is responsive to a request, produce the

entire document, including all attachments, enclosures, "post-it"-type notes, and any other matter physically attached to the document. If a document responsive to any request cannot be produced in full, it shall be produced to the extent possible with an explanation stating why production of the remainder is not possible.

3. If a document responsive to any request is no longer in your possession, custody, or control, state: (i) its date; (ii) author(s); (iii) recipient(s); (iv) subject matter; (v) when such document was most recently in your possession, custody, or control; (vi) what disposition was made of the document; and, (vii) the person or entity, if any, now in possession, custody, or control of the document. If a document has been destroyed, identify: (i) the date of destruction; (ii) the person who destroyed the document(s); (iii) the person who directed the document to be destroyed; and, (iv) the reason(s) for its destruction.

4. All documents produced in response to these requests shall be produced in the same order as they are kept in the ordinary course of business and, where attached, shall not be separated or disassembled. If documents responsive to any request are normally kept in a file or folder, also produce that file or folder with any labels attached thereto, and indicate the company, division, department, and/or individual from whose files the document is being produced. If responsive documents are segregated or separated from other documents, whether by inclusion in binders, files, sub-files, or by use of dividers, tabs or any other method, produce such documents in that form.

5. If, in responding to these document requests, you claim any ambiguity in interpreting either a request or a definition or instruction applicable thereto, such claim shall not be utilized by you as a basis for refusing to respond, but you shall set forth as part of your

response to the request the language deemed to be ambiguous and the interpretation chosen to be used in responding to the request.

6. If, in responding to these document requests, you assert a privilege to any particular request, you must identify the nature of the privilege (including work product) that is being claimed, and, if the privilege is governed by state law, indicate the state's privilege rule being invoked. In addition, the following information shall be provided in the objection:

- a. For documents: (i) the type of document; (ii) the general subject matter of the document; (iii) the date of the document; and (iv) such other information as is sufficient to identify the document for a subpoena duces tecum, including, where appropriate, the author of the document, the addressees of the document, and any other recipients shown in the document, and, where not apparent, the relationship of the author, addressees, and recipients to each other;
- b. For oral communications: (i) the name of the person making the communication and the names of persons present while the communication was made and, where not apparent, the relationship of the persons present to the person making the communication; (ii) the date and place of communication; and (iii) the general subject matter of the communication.

7. Each request for documents is continuing in nature. If, after responding to these requests, you obtain or become aware of further documents responsive to any request, such documents shall be produced promptly in accordance with Rule 26(e) of the Federal Rules of Civil Procedure and the definitions and instructions herein.

DOCUMENT REQUESTS

1. All documents concerning, relating, or referring to the '318 patent, including but not limited to:

- (a) all documents surrounding the alleged invention of the '318 patent, including but not limited to, all documents and/or things that you considered in connection with the development of the invention allegedly disclosed in the '318 patent, and/or in connection with the prosecution of the patent, regardless of whether such documents or information was cited to the PTO;
- (b) all documents relating to Claims 1 and 4 of the '318 patent, including the dosage amounts in Claim 4;
- (c) all laboratory notebooks or other documents relating to or concerning the conception and/or reduction to practice of the alleged invention of the '318 patent, including but not limited to, (i) documents concerning the identity of the individuals who allegedly conceived of, and/or reduced to practice or assisted in the reduction to practice of, the invention claimed, and (ii) documents concerning the date(s) on which such alleged conception and/or reduction to practice occurred;
- (d) all inventor disclosure statements;
- (e) all documents concerning the subject matter of the '318 patent;
- (f) all documents concerning or relating to any contract, agreement, grant, sponsorship or compensation paid or received in connection with any tests, studies, analyses, investigations, reports, comparisons or opinions conducted, prepared, or performed concerning or relating to the subject matter described and/or claimed in the '318 patent and the prosecution of the '318 patent; and
- (g) all documents concerning or relating to any tests, studies, analyses, investigations, reports, comparisons, or opinions concerning or relating to the '318 patent, including but not limited to any contract, agreement, grant, sponsorship or compensation paid or received in connection with any such tests, studies, analyses, investigations, reports, comparisons or opinions.

2. All documents concerning or relating to the prosecution of the '318 patent, including but not limited to:

- (a) all documents relating to the filing and prosecution of the '318 patent, including but not limited to, (i) the preparation and drafting of Application No. 819,141; (ii) any and all literature reports, prior art, or other documents, regardless of whether such information was cited to the PTO, reviewed, considered, analyzed or otherwise referenced in considering to prosecute or in prosecuting the '318 patent; and (iii) testing results or any other documents supporting the prosecution and/or claims of the '318 patent.
- (b) all documents submitted or otherwise received from the PTO in connection with the filing and prosecution of the '318 patent;
- (c) all documents concerning (i) the "experiments underway using animal models" and (ii) the "survey of drugs" as referenced in the Amendment Responsive to Office Action of April 10, 1986, submitted on your behalf during the prosecution of the '318 patent, including the person(s) or entity(ies) performing any experiments and the person(s) or entity(ies) funding any experiments;
- (d) all documents supporting the statement in the Amendment Responsive to Office Action of April 10, 1986, submitted on your behalf during the prosecution of the '318 patent, that "[g]alanthamine and its properties have been known for many years";
- (e) all documents concerning the rejection by the PTO of the claims of the '318 patent, including as being indefinite and unpatentable, including but not limited to, all documents referenced, relied upon, supporting, concerning or otherwise relating to the Amendment Responsive to Office Action of April 10, 1986, submitted on your behalf, including all drafts of such Amendment.
- (f) all prior art or potential prior art collected, considered or otherwise reviewed with respect to the '318 patent, whether or not submitted to the PTO, and all articles, patents, publications or studies concerning, in whole or in part, galantamine that issued or published prior to January 15, 1986.

3. All documents and things concerning, relating, or referring to any license, offer to license or other agreement, assignment, transfer or lien, or contingent or future interest in the '318 patent, including any payments, compensation or royalties paid to or otherwise received by you or on your behalf.

4. All documents and things concerning, relating, or referring to galantamine, including but not limited to:

- (a) any testing or experiments conducted or funded by you or on your behalf, either directly or indirectly, or under your direction, with galantamine, including but not limited to, testing on patients with Alzheimer's disease, animals, or normal humans;
- (b) documents concerning or relating to any use of or treatment with galantamine (whether actual or proposed), including but not limited to, treatment on patients with Alzheimer's disease or use in post-operative recovery from anaesthesia;
- (c) any reports, publications, articles or patents concerning, referring to or relating to galantamine, including, but not limited to, such documents for which you are an author or co-author; and
- (d) all agreements concerning the rights to market and/or sell galantamine in the United States.

5. All documents and things concerning, relating, or referring to Alzheimer's Disease, including but not limited to:

- (a) any testing performed on persons with Alzheimer's Disease;
- (b) any reports, publications, articles or patents concerning, referring to or relating to Alzheimer's Disease, including but not limited to, such documents for which you are an author or co-author; and
- (c) all documents and things concerning, referring to or relating to the market for drugs used for the treatment of mild to moderate dementia of the Alzheimer's type, including, but not limited to, documents identifying all drugs used for the treatment of mild to moderate dementia of the Alzheimer's type.

6. Any and all communications with, between or among Janssen, Janssen Pharmaceutica, Synaptech, Intelligen, Bonnie Davis and/or any other person or entity relating, concerning, or relating to:

- (a) the '318 patent;
- (b) the Current Litigation;
- (c) any Related Litigation;
- (d) the alleged invention of the '318 patent;
- (e) Application No. 819,141, including the filing of that application;

- (f) the prosecution of the '318 patent;
- (g) any ANDA referencing NDA No. 21-169;
- (h) any notification received under 21 U.S.C. § 355(j) referencing NDA No. 21-169;
- (i) galantamine hydrobromide; and
- (j) acetylcholinesterase inhibitors, including but not limited to physostigmine.

7. All documents concerning NDA No. 21-169, including but not limited to studies, papers or documents cited in the NDA.

8. All documents and things concerning physostigmine or any acetylcholinesterase inhibitor, including, but not limited to:

- (a) any testing or experiments conducted or funded by you or on your behalf, either directly or indirectly, or under your direction, with physostigmine, including but not limited to, testing on patients with Alzheimer's disease, animals, or normal humans; and
- (b) any reports, publications, articles or patents concerning, referring to or relating to physostigmine or acetylcholinesterase, including but not limited to, such documents for which you are an author or co-author.

9. Personnel file, including but not limited to:

- (a) most update resume; and
- (b) list of all articles published to date for which you have authored or co-authored.